IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		Docket No.:	4258-117
Applicants:	ALONSO FERNANDEZ, Maria Jose, et al.	Conf. No.:	6063
Application No.:	10/563,031	Art Unit:	1618
Date Filed:	December 30, 2005	Customer No.:	23448
Title:	NANOPARTICLES OF POLYOXYETHYLENATED DERIVATIVES)))	

EFS FILING CERTIFICATE

I hereby certify that this document is being filed in the United States Patent and Trademark Office, via EFS submission, on **May 6, 2009**.

/steven j. hultquist/

Steven J. Hultquist

May 6, 2009

Date

SUBMISSION OF DECLARATION (CFR 1.132) OF ANA ISABEL VILA PENA AND BALBINA FERNANDEZ MARTINEZ IN U.S. PATENT APPLICATION NO. 10/563,031

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

Enclosed and submitted herewith is a Declaration of Ana Isabel Vila Pena and Balbina Fernandez Martinez Under 37 CFR 1.132 attesting to facts concerning empirical work conducted by them relevant to the invention of the above-identified patent application.

4258-117-RCE

It is requested that the examiner take cognizance of this Declaration evidence relating to

comparative testing of a composition according to Grandfils U.S. Patent 5,962,566 containing a

cholesterol compound, against a corresponding composition lacking such cholesterol component

(Grandfils teaching a cholesterol compound to be required).

The results show that nanoparticles cannot be achieved in the process of Grandfils without

cholesterol, and that cholesterol is necessary in such process to produce nanoparticles.

It is pointed out that the Response to the March 30, 2009 Advisory Action, filed with an

accompanying RCE, amended the pending claims to exclude the presence of a cholesterol

compound in the method and composition of applicants' claimed invention.

The enclosed Declaration under 37 CFR 1.132 is therefore submitted to provide additional

evidentiary support for the patentability of applicants' claims over the Grandfils reference, cited

as anticipating applicants' previously pending claims 1-3, 6-7 and 10-17, and as rendering

previously pending claims 1-17 obvious in view of Levy et al. WO 96/20698. As previously

pointed out, in the April 20, 2009 Response filed by applicants, the hypothesized modification of

Grandfils based on Levy does not alter the compositional requirement of Grandfils for a

cholesterol compound.

Accordingly, since applicants' claims were amended in such April 20, 2009 Response to exclude

the presence of a cholesterol compound, and since the accompanying Declaration empirically

verifies the requirement of the Grandfils process to utilize a cholesterol compound in order to

achieve nanoparticles, consistent with Grandfils' own teaching, it is submitted that claims 1-20

are now fully patentably distinguished over the art and in form and condition for allowance.

It is therefore requested that a Notice of Allowance be issued for the application.

Respectfully submitted,

/steven j. hultquist/

Steven J. Hultquist

Reg. No. 28,021

Attorney for Applicants

2

INTELLECTUAL PROPERTY/ TECHNOLOGY LAW Phone: (919) 419-9350 Fax: (919) 419-9354 Attorney File No.: 4258-117-RCE

Enclosures:

Executed Declaration of Ana Isabel Vila Pena and Balbina Fernandez Martinez [3 pgs.]

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284